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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,520	12/07/2007	Martyn Pritchard	13425-200US1 BV-1093 US	6818
26161 7590 08/19/2011 FISH & RICHARDSON P.C. (BO) P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER MCINTOSH III, TRAVISS C	
			ART UNIT 1623	PAPER NUMBER
			NOTIFICATION DATE 08/19/2011	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/598,520	Applicant(s) PRITCHARD ET AL.
	Examiner TRAVISS C. MCINTOSH III	Art Unit 1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,29,30,32-56,58,59 and 77-94 is/are pending in the application.
- 4a) Of the above claim(s) 30 and 32-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,58 and 77-83 is/are rejected.
- 7) ☒ Claim(s) 2,4,5,29,59 and 84-94 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/26/11</u> . | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) <input type="checkbox"/> Notice of Informal Patent Application
6) <input type="checkbox"/> Other: _____. |
|---|--|

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DETAILED ACTION

The Amendment filed 5/26/11 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 1-5, 29-30, 32-33, 35, 37-38, 40-46, and 48-55 have been amended.

Claims 6-28, 31, 57, and 60-76 have been canceled.

Claims 77-94 have been added.

Claims 30 and 32-56 stand as being withdrawn.

Remarks drawn to rejections of Office Action mailed 11/26/2010 include:

Claim objections: which have been overcome by applicants' amendments and have been withdrawn.

112 2nd paragraph rejections: which have been overcome by applicants' amendments and have been withdrawn.

102(b) rejection: which has been overcome by applicant's amendments and has been withdrawn. Specifically, as applicants noted, the compounds administered in Marumoto were administered directly into the coronary artery of anaesthetized, open-chest dogs through the polyethylene catheter at doses of 0.1-100µg/dog.

103(a) rejection: which has been maintained in part for reasons of record. It is noted the rejection has been withdrawn over claims 2-5 and 29 based on applicant's arguments regarding *Takeda Chem. Indus., Ltd v Alphapharm Pty., Ltd*. The examiner agrees that compounds 5d, 5o, 5p, and 5q would not be selected as lead compounds in viewing

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Marumoto as these compounds have weak potency compared to other compounds therein.

Likewise, the examiner would like to note that claim 59 should be examined with the elected group I and will be examined herein.

An action on the merits of claims 1-5, 29, 58-59, and 77-94 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 77-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsuda et al. (Chem. Pharm. Bull., 27(1), 1979, 183-192).

Matsuda discloses a compound which comprises CONH₂ in the instant R₁ position which is the same as instant compound 39. See compound 24 on page 185.

Claims 77 is rejected under 35 U.S.C. 102(b) as being anticipated by US 4,225,591.

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The '591 patent discloses a compound having a F-substituted phenylamino group. See compound in example #6 in column 10.

Claims 77-79 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,255,565.

The '565 patent discloses a compound having a 4-F-substituted phenylamino group. See compound in example 14 in column 11. this is seen to be the same as compound 28 of the instant application.

Claims 77-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Bressi (J. Med. Chem., 2000 vol. 43, pp. 4135-4150.

Bressi et al. disclose a compound which is the same as that of compound 29 on the instant application. See compound 21c in Bressi.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1 and 58 under 35 U.S.C. 103(a) as being unpatentable over Marumoto is maintained for reasons of record. Likewise, claims 80-83 are also rejected herein.

The claims of the instant application are drawn to various compounds and compositions comprising the same.

Marumoto disclose compounds overlapping in scope with the instantly claimed compounds used in the compositions of claims 1 and 58. What is not taught are compositions comprising the same wherein there is a physiologically acceptable carrier, excipient, or diluent.

However, it is well settled that a composition (composition plus carrier) is allowable only if no utility is disclosed for the old compound. See *Ex parte Erdmann*, 194 USPQ 96. It is obvious to add a carrier to an obvious compound. See *Ex parte Douros*, 163 USPQ 667 (PTO *Bd. App.* 1968). In the instant case, Marumoto et al. teach that the compounds are effective as

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coronary vasodilators. As such, the compositions claimed are seen to be obvious in light of the teaching of the compounds and a utility therefor.

Claims 1, 3, 58 and 77-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bressi (J. Med. Chem., 2000 vol. 43, pp. 4135-4150).

Bressi et al. disclose a compound comprising an NH-cyclopentyl group in the R₁ position of the instant application. See compound 21c. What is not specifically exemplified is a composition comprising the same.

However, it is well settled that a composition (composition plus carrier) is allowable only if no utility is disclosed for the old compound. See *Ex parte Erdmann*, 194 USPQ 96. It is obvious to add a carrier to an obvious compound. See *Ex parte Douros*, 163 USPQ 667 (PTO Bd. App. 1968). In the instant case, Bressi et al. teach that the compounds are effective as in inhibiting African trypanosomiasis. Likewise, African trypanosomiasis is known to be a disorder which affects humans and oral administration of drugs to humans, such as in tablets or capsules, is a normal procedure. As such, the compositions claimed are seen to be obvious in light of the teaching of the compounds and a utility therefor.

Conclusion

Claims 2, 4-5, 29, 59, and 84-94 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **TRAVISS C. MCINTOSH III** whose telephone number is (571)272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TRAVISS C MCINTOSH III/
Primary Examiner, Art Unit 1623
August 14, 2011